

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/666,146	RIETHMULLER-WINZEN ET AL
	Examiner San-ming Hui	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to \_\_\_\_\_.
2.  The allowed claim(s) is/are 1-13 and 28-31.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 12-3-04
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

## REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: in view of the decision of the Board of Patent Appeals and Interferences in March 17, 2005.

In the decision, the Board of Patent Appeals and Interferences cite three articles for the Examiner to consider the patentability of the instant claims. After considering the articles, Examiner found that these articles do not adversely affect the patentability of the claims. Specifically, Reissmann article published in Human Reproduction in 1994 merely hypothesizes that the LHRH-antagonist, based on its described mechanism of action, might be useful in treating endometriosis with reduced treatment duration. As for the treatment of leiomyomas using LHRH antagonists, no teachings as to the duration, or effectiveness of LHRH-antagonists are disclosed. These teachings are speculative at best. Furthermore, there are no clear teachings with regard to the effectiveness of such treatment. Moreover, although leiomyomas is associated with pelvic pain, not all leiomyomas patients will suffer from pelvic pain, let alone chronic pelvic pain. Kettel article from Fertility and Sterility teaches a method of employing LHRH-antagonists in treating leiomyomas. However, as discussed above, not all leiomyomas patients will suffer from pelvic pain, let alone chronic pelvic pain. Kettel's study did not measure any parameters with regard to the pelvic pain, or chronic pelvis pain. The endpoint of Kettel's study is the size of tumor. However, as one of ordinary skill in the art aware of, the size of the tumor may or may not correlate the relief of the symptoms. As for Reissmann et al., in Human Reproduction, 1995, teaches the relationship of Estradiol level and the administration of LHRH antagonists. Since there is no motivation to

employ LHRH antagonists to treat the herein claimed conditions, the relationship between the level of estradiol and the administration of LHRH antagonists is moot. Therefore, Examiner does not see these articles do not affect the patentability of the instant claims.

Claims 1-13 and 28-31 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui  
Primary Examiner  
Art Unit 1617